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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,721	12/14/2001	Motonao Nakao	HIRA.0054	9615

7590

04/08/2003

Stanley P. Fisher  
REED SMITH LLP  
3110 Fairview Park Drive Suite 1400  
FALLS CHURCH, VA 22042

EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

10

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/020,721		NAKAO ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Suryaprabha Chunduru		1637	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 January 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

1. Applicants' response to the office action and amendment (Paper No. 9) filed on January 17, 2003 has been entered.

***Response to Arguments***

2. Applicant's response to the office action (Paper No.9) is fully considered and deemed persuasive.

3. With reference to the rejection maintained in the previous office action under 35 U.S.C.112 second paragraph, applicants' arguments and amendment have been fully considered and the rejection is withdrawn herein.

4. With reference to the rejection made in the previous office action under 35 U.S.C. 103(a), applicants' arguments and amendment have been fully considered and the rejection is moot in view of the new grounds of rejection.

**New Grounds of Rejection necessitated by the Amendment**

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim 1 recites "conducting a hybridization reaction by using a substrate on which said primers used for the PCR are fixedly spotted...". The phrase "said primers" is indefinite and unclear for two reasons, first, it is not clear whether hybridization

reaction includes a single PCR primer pair or second, whether all PCR primers are used in the hybridization reaction. Hence the meets and bounds of the claims are unclear.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Schollien et al.

(Clin Chem., Vol. 43, No. 1, pp. 18-23, 1997).

This rejection is made considering first alternative reason (a pair of PCR primers used for hybridization reaction) as discussed in the above rejection under 35 USC 112 second paragraph.

With reference to the instant claim 1, Schollien et al. teach a method of detecting PCR-amplified base sequences wherein Schollien et al. disclose that the method comprises (i) conducting PCR amplification by mixing a plurality of pairs of primers with a sample (see page 19, column 1, paragraph 3), said primers being suitable for amplifying different base sequences of a same or different lengths by PCR (see page 19, Table 1, see fragment lengths); (ii) conducting a hybridization reaction by using a substrate on which said PCR primers are fixed, and a hybridization solution containing said PCR amplified sequences (see page 19, column 1, paragraph 3, column 2, paragraph 1); detecting the hybridization spot on the substrate in which hybridization reaction occurred (see page 19, column 2, paragraph 1). Schollien et al. also disclose the oligonucleotides on the substrate are equivalent to the PCR primers used in the amplification (see page 20, paragraph 1, column 2, paragraph 4).

With reference to the instant claims 2-4, Schollien et al. teach that (i) the detection PCR-amplified base sequences comprise fluorescent agent and measuring signal generated by the fluorescence reagent (see page 19, column 2, paragraph 1); the said PCR primers comprise a base length number ranging from 10-30 (see page 19, table 1, page 20, table 2). Thus the disclosure of Schollien et al. meets the limitations in the instant claims.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Schollien et al. (Clin Chem., Vol. 43, No. 1, pp. 18-23, 1997). And in view of Longiaru et al. (USPN. 5,232,829).

This rejection is made considering second alternative reason (all PCR primers used as probes for hybridization reaction) as discussed in the above rejection under 35 USC 112 second paragraph.

Schollien et al. teach a method of detecting PCR-amplified base sequences wherein Schollien et al. disclose that the method comprises (i) conducting PCR amplification by mixing a plurality of pairs of primers with a sample (see page 19, column 1, paragraph 3), said primers being suitable for amplifying different base sequences of a same or different lengths by PCR (see page 19, Table 1, see fragment lengths); (ii) conducting a hybridization reaction by using a substrate on which said PCR primers are fixed, and a hybridization solution containing said PCR amplified sequences (see page 19, column 1, paragraph 3, column 2, paragraph 1); detecting the hybridization spot on the substrate in which hybridization reaction occurred (see page 19, column 2, paragraph 1). Schollien et al. also disclose the oligonucleotides on the substrate are equivalent to the PCR primers used in the amplification (see page 20, paragraph 1, column 2, paragraph 4). Schollien et al. teach that (i) the detection PCR-amplified base sequences comprise fluorescent agent and measuring signal generated by the fluorescence reagent (see page 19, column 2, paragraph 1); the said PCR primers comprise a base length number ranging from 10-30 (see page 19, table 1, page 20, table 2). However Schollien et al. did not specifically teach said PCR primers used as probes in hybridization reaction.

Longiaru et al. teach a method for detection of a microorganism using a format for hybridization capture of PCR amplified DNA on a solid support wherein Longiaru et al. disclose PCR primers themselves could be used as capture probes in hybridization reaction (see column 7, lines 1-20).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of detecting PCR-amplified base sequences as taught by Schollien et al. with the method as taught by Longiaru et al. which is applicable to use PCR primers as probes because Longiaru et al. states that 'capture probes are defined herein as sequences of amplicon within the boundaries of the primers, the primers themselves or oligonucleotides containing primer sequences, may be used as capture probes' (see column 7, lines 12-20). An ordinary practitioner would have been motivated to combine the method of Schollien et al. with the teachings of Longiaru et al. for the advantages of developing a sensitive method for detecting PCR-amplified base sequences by including the PCR primers as capture probes in hybridization reaction because such limitation would enhance the detection of PCR-amplified base sequences by reducing non-specific hybridization.

### ***Conclusion***

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Suryaprabha Chunduru  
April 2, 2003

  
JEFFREY FREDMAN  
PRIMARY EXAMINER